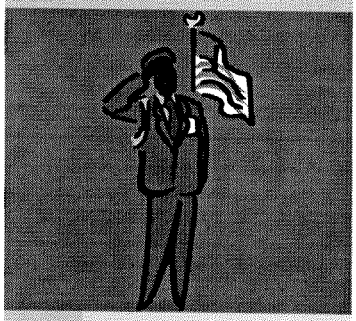
September/October 2001

Editor:
Jean Ellertson, PharmD



The Apothecary Bulletin

PHARMACY SERVICE & THERAPEUTICS COMMITTEES
US ARMY MEDDAC, FORT CARSON, COLORADO

FORMULARY CHANGES

The Pikes Peak Region Formulary Committee meet on 6 September 2001 with the following medications ***added*** to the Formulary (the Evans' September P&T meeting was postponed):

+ clarithromycin 500mg extended release tablets (*Biaxin XL*)
+ metformin 500mg extended release tablets (*Glucophage XR*)
+ pioglitazone tablets (*Actos*) — **as with *Avandia*, recommended to check LFTs as follows: baseline, every 2 months for 12 months, and periodically thereafter**
+ rabeprazole 20mg delayed release tablets (*Aciphex*) — ***** pharmacy autoconversion approved — patients on *Prilosec* will be changed to *Aciphex* on a mg-per-mg basis by the pharmacy for all military providers; *Prilosec* will only be approved for the treatment of *H. pylori* (14 day supply) or for the treatment of gastric ulcer (30 day supply)**

The following medications were ***deleted*** from the Formulary:

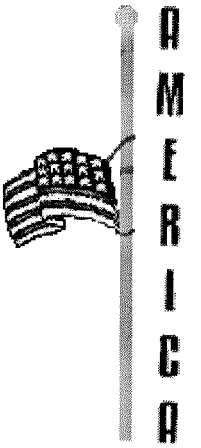
- cerivastatin (*Baycol*) — **no longer being manufactured**
- nitroglycerin SL 0.3mg and 0.6mg tablets — **0.4mg SL tablets remain on formulary**
- pemoline (*Cylert*) — **requires every 2 week LFT monitoring along with signature of parent/patient understanding of risk**

As part of the ongoing drug class review process, the Pikes Peak Region Formulary Committee (with representatives from the Air Force Academy, Peterson AFB, and Evans) will conduct reviews as follows:

November 2001 = gastrointestinal/renal/genitourinary
January 2002 = central nervous system
March 2002 = dermatologic/ophthalmologic

Pharmaceuticals submitted for Formulary consideration will be reviewed based on the above schedule. If a medication is a new entity, it may be considered earlier than the above schedule if submitted via a New Drug Request.

Providers desiring to have input into the drug class reviews are encouraged to contact one of the committee members: **LTC Edward Torkilson (Pharmacy), MAJ Robert Gray (Family Practice), and Dr. Garold Paul (Internal Medicine).** The next Formulary Committee Meetings will be held on 1 November 2001 (Pikes Peak) and 13 November 2001 (Evans' P&T). New Drug Requests must be received by the Chief, Pharmacy Service, no later than **26 October** to be considered at the November meetings.



"From every mountainside,
let freedom ring!"

Samuel Francis Smith,
"America", 1831

Q & A

What is Evans' definition of an ADR and what are the options for reporting an adverse drug event at Evans?

see page 4

CONGRATULATIONS TO

JOHN ASHCRAFT

NEW OUTPATIENT PHARMACY SUPERVISOR!!

In this issue....

ZOLOFT STARTER KIT

Sertraline (*Zoloft*) Starter Packs are now available at the pharmacy for all **NEW** patients being started on *Zoloft*. The kit includes seven 25mg tablets and fourteen 50mg tablets along with patient educational information on Depression, Panic/Anxiety, Posttraumatic Stress Disorder (PTSD), and Obsessive Compulsive Disorder (OCD). If you choose to start a patient on *Zoloft* using the Starter Pack, please enter 2 prescriptions: one for the Starter Pack (instructions will already be entered in CHCS for the Starter Pack) and an additional prescription for continuation of therapy after the Starter Pack is completed. You will receive a warning for a "class overlap" but can override without canceling either prescription.

The literature suggests this approach may be beneficial for several reasons. By starting out slower, the patient may experience fewer side effects which can improve compliance with completing their course of antidepressant therapy. As a result, more people should stay on their medication with a decreased percentage of relapse due to partial treatment of their depressive symptoms. This new "stepped care" approach should also help determine the lowest effective dose for each individual patient. The higher the daily dose, the more potential side effects for the patient along with a greater cost of therapy.

"Wine is at the head of all medicines;
where wine is lacking,
drugs are necessary."
- Babylonian Talmud, 450 A.D.

INFLUENZA GUIDELINE

History

On **June 14, 1777**, Congress made the following resolution: "The flag of the United States shall be thirteen stripes, alternate red and white, with a union of thirteen stars of white on a blue field."

In **September 1814**, Francis Scott Key wrote *The Star Spangled Banner* during the conflict between Fort M'Henry and the British Fleet.

In **1901**, Booker T. Washington's autobiography *Up From Slavery* is published.

In **1903**, the first silent movie, *The Great Robbery*, is a great success.

In **1927**, the first pop-up toaster is design in the U.S.

On **May 21, 1927**, Charles Lindbergh becomes the first man to fly solo across the Atlantic Ocean.

In **1928**, Walt Disney makes his first Mickey Mouse cartoon.

In **1933**, the first U.S. aircraft carrier launched.

On **December 5, 1933**, the 21st Amendment is added to the Constitution, repealing Prohibition.

In **1936**, Margaret Mitchell writes *Gone with the Wind.*

In **1953**, an American company develops the first microwave oven.

In **1960**, the first laser device is developed by U.S. scientists.

In **1961**, President John F. Kennedy establishes the U.S. Peace Corps.

NEW INDICATIONS/DRUGS

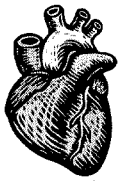
Topamax (topiramate) has received FDA approval as an adjunctive treatment in adults and children (aged 2 to 16 years) who suffer from seizures associated with Lennox-Gastaut Syndrome.

The FDA has approved *Xeloda* (capecitabine), an oral cancer drug, in combination with *Taxotere* (docetaxel), an IV cancer drug, for the treatment of metastatic breast cancer in patients whose anthracycline treatment has failed. The combination of *Xeloda* and *Taxotere* is the first and only chemotherapy combination to significantly extend survival in these patients compared to *Taxotere* alone — median survival extended by 3 months over *Taxotere* alone (median survival 14.5 months versus 11.5 months).

The FDA has approved *Cathflo Activase* (alteplase) for the restoration of function to central venous access devices (CVADs), as assessed by the ability to withdraw blood. The approval of *Cathflo Activase* is based on two Phase III clinical trials designed to assess its safety and efficacy in restoring function to CVADs that had become occluded due to a blood clot. Neither study included patients with hemodialysis catheters, known mechanical occlusions, or those at high risk for bleeding or embolization.

Patient Education Displays are located in pharmacy waiting area.

September is ...
National Cholesterol Awareness Month



October is ...
Breast Cancer Awareness Month

WEBSITES OF INTEREST

http://evans.amedd.army.mil – Evans' page
http://evans.amedd.army.mil/pharmnew/ — Evans' pharmacy website; access to the Formulary, *Herbal-Drug Interaction Chart*, Drug Information
http://www.pec.ha.osd.mil – DoD Pharmacoeconomic Center, Ft Sam Houston
http://www.cs.amedd.army.mil/qmo/pguide.htm – DoD/VHA Practice Guidelines; current guidelines include Low Back Pain, Asthma, Diabetes, COPD, Hypertension, Hyperlipidemia, Tobacco Use Cessation, Major Depressive Disorder, Dysuria in Women

Cholesterol Websites

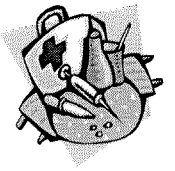
http://www.nhlbi.nih.gov/index.htm — NHLBI's National Cholesterol Education Program; includes the *Clinical Practice Guidelines for Cholesterol Management in Adults* (ATPIII)
http://www.heartinfo.org — Heart Information Network
http://www.healthtouch.com — Health Touch Online; good patient information on a variety of topics; click on "Health Information" and search for "cholesterol"; gives information on Heart Disease & Women, The Connection Between High Blood Cholesterol & Heart Disease, information on Step I & Step II Diets, etc

Breast Cancer Websites

http://www.nbcam.org — National Breast Cancer Awareness Month
http://www.cancerhelp.com/ed — Edu-Care Inc.; Breast Health & Breast Cancer Network
http://www.breastcancerinfo.com — The Susan G. Komen Breast Cancer Foundation
http://www.y-me.org — Y-ME National Breast Cancer Organization (English or Spanish)
http://www.nabco.org — National Alliance of Breast Cancer Organizations
http://commtechlab.msu.edu/sites/bcl/index.html — Breast Cancer Lighthouse
http://interact.withus.com/interact/mbc — Breast Cancer in Men

In you, O Lord, I take refuge...
Incline your ear to me, and save me.
Be my rock of refuge,
A stronghold to give me safety.
— Psalm 71

ADVERSE DRUG REACTION REPORT



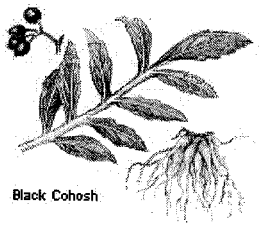
There were 31 adverse drug reactions (ADRs) documented for July (n=15) and August (n=16), of which 14 (45%) were reported **spontaneously** (5 from Internal Medicine; 4 from outpatient pharmacy; 2 from Family Practice; and 1 each from Dermatology/Internal Medicine, inpatient pharmacy, and Pediatrics). The most prevalent adverse events involved the anti-infective agents (n=12; 39%), the analgesic agents (n=6; 19%), and the cardiovascular agents (n=4; 13%). The anti-infective agents continue to be the top medication class involved in the reported adverse events. The rate of outpatient ADR reporting has remained consistent over the last year.

One event was deemed moderate on the severity scale (mild, moderate, severe, fatal): a 27 year old male who was hospitalized for 4 days for hypersensitivity syndrome due to minocycline. The patient experienced mild hepatitis (maximum AST 237, ALT 362 - baseline and follow-up LFTs normal), slightly raised macularpapular rash, persistent fevers to 105°F, inguinal lymphadenopathy, pharangeal ulcers, headaches, and increased Scr (to 1.5 - no baseline, follow-up 0.9).

One event (possibly due to drug received) was deemed severe: a 28 year old female who experienced respiratory arrest while being prepped for same day surgery who received half a bag of *Cefotan* 2gm (manufacturer premixed product). She suddenly developed mild seizures and respiratory arrest, code blue was called, and patient was stabilized and moved to the ICU where she remained overnight for observation. The patient was discharged the following day.

Thank you to all providers who continue to report adverse events.

HERB OF THE (every other) MONTH


Black Cohosh

Black cohosh (*Cimicifuga racemosa*), also known as black snakeroot, squaw root, and rattel root, grows in shady rich soil in the woods of the eastern deciduous forests from southern Ontario south to Georgia, west to Arkansas, north to Wisconsin. First described by botanists in 1705, the roots and rhizomes are used medicinally. Traditional uses include the treatment of dysmenorrhea, dyspepsia, and rheumatisms. American Indian groups of eastern North America used the root of black cohosh for a variety of ailments, including menstrual cramps and pain associated with labor and delivery, long before Europeans landed on American shores. Eclectic physicians in the U.S. during the 1800s used this herb to treat uterine difficulties, stimulate menstrual flow, and reduce discomfort during labor (it was one of the main ingredients in Lydia Pinkham's *Vegetable Compound*). The "black" refers to the dark color of the rhizome, and the "cohosh" comes from an Algonquian word meaning "rough," referring to the feel of the rhizome.

Little is known about the composition of the plant although the steroidal terpene actein, cimigoside, and 27-deoxyactein have been isolated. The plant also contains a tannin and the isoflavone, formononetine. In women treated for 8 weeks with the commercial product *Remifemin* (an ethanolic extract of *C. racemosa* used for the management of menopausal hot flashes), leuteinizing hormone but not follicle-stimulating hormone levels were reduced significantly. Analysis of the commercial product suggested the presence of at least three fractions that contribute synergistically to the suppression of LH and bind to estrogen receptors.

Used in Europe for over 40 years, the German Commission E has approved black cohosh for the treatment of menopausal symptoms. The dose approved by the Commission E is 40mg per day with the recommendation that women use it for no longer than 6 months continuously. Black cohosh can take at least 3 to 4 weeks before the effect kicks in. The FDA lists black cohosh as an herb of "undefined safety."

Occasional stomach pain or intestinal discomfort has been reported with the use of black cohosh, likely due to the high tannin content. An overdose (over 900 mg/day) could cause dizziness, nausea, vomiting, diarrhea, pain in the abdomen, headaches, joint pains, and a lowered heart rate. It is advised not to mix black cohosh with birth control pills, HRT, sedatives, or blood pressure medication. Black cohosh is contraindicated in pregnancy, and large doses could result in miscarriage.

References: The Review of Natural Products, Various Websites

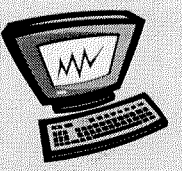
Q & A

EVANS' ADR DEFINITION

An adverse drug reaction (ADR) is any **unexpected, undesired, and unintended effect** of a drug following prescribed doses that (1) requires some sort of management including, but not limited to, discontinuation of the causative medication or treatment with another drug; (2) adversely impacts the outcome or progress of the patient's clinical condition; or (3) results in death, hospitalization, prolongation of hospital stay, transfer to a more intense level of care, or significant discomfort/distress to the patient.

HOW TO REPORT AN ADR

- Complete the **Adverse Drug Reaction Reporting Form** and return to the pharmacy. For additional forms, call the pharmacy at 526-7334.
- Use **CHCS e-mail and send to mail group "G.ADR"**. Please include the patient's name and SSN, date of occurrence, suspected drug, signs/symptoms of the event, and any changes/additions to therapy made.



- Use **Website ADR Reporting** option located on the Evans Pharmacy Webpage. From the Evans Homepage, choose "Medical Clinics", then "Pharmacy", then search for "ADR" and follow the instructions. Reported ADRs are confidentially forwarded to the ADR Coordinator's e-mail.

- **Phone-in** the ADR to **52 I-ITCH** (524-4824). Please include the patient's name and SSN, date of occurrence, suspected drug, signs/symptoms of the event, and any changes/additions to therapy made. Make sure you include your name and extension in case more information or follow-up is needed.

- **Phone-in** the ADR to the Inpatient Pharmacy at 524-4400 from 0600 to 2300 or call 526-7334 and leave a voice mail message with the information listed above. Make sure you include your name and extension in case more information or follow-up is needed.